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PhRMA

October 8, 2009
VIA ELECTRONIC MAIL

Hon. Lawrence Bliss, Senate Chair
Hon. Charles Priest, House Chair
Joint Standing Committee on Judiciary
c/o Office of Policy and Legal Analysis
13 State House Station
Augusta, Maine 04333

Re: PhRMA Comments on Public Law 2009, Chapter 230, An Act To Prevent Predatory Marketing Practices against Minors

Dear Senator Bliss and Representative Priest:

The Pharmaceutical Research and Manufacturers of America (PhRMA) is a voluntary, non-profit organization representing the country's leading pharmaceutical research and biotechnology companies. In 2008, PhRMA members invested approximately $50.3 billion to develop new medicines to allow patients to live longer, healthier, and more productive lives. PhRMA is pleased to offer these comments to assist the Maine Legislature in fulfilling its goal of protecting minors while respecting constitutional limitations on the restriction of commercial speech. PhRMA has identified the following concerns with Public Law 2009, chapter 230:

- **The broad definition of "Health-related information" draws into the statute too much general information.** The current definition of "Health-related information," in section 9551(1) is so broad that the prohibition against using health-related information for marketing purposes could subject pharmaceutical manufacturers to liability for merely hosting web pages where users can request information about diseases, conditions, or treatment options, even if the web site was not directed towards minors. For example, a company that hosted a web page where users could request information about a product related to a common disease in adolescents (e.g. acne) or a health issue that the company knows is of increasing importance to adolescents (e.g. diabetes, weight control) could face liability, even if requesting the information did not require the minor to share individually identifiable information. Maine's medical privacy law already defines "health care information" as "information that directly identifies the individual and that relates to an individual's physical, mental or behavioral condition, personal or family medical history or medical treatment or the health care provided to that individual." ME. REV. STAT. ANN. tit.

tit. 22, § 1711-C(1)(E) (2008). This definition is modeled on the federal definition of "health information" in the regulations implementing the Health Insurance Portability and Accountability Act (HIPAA) define "health information" as information that created or received by certain specified entities that "relates to the past, present or future physical or mental health of an individual, the provision of health care to an individual; or the past, present or future payment for the provision of health care to an individual." *See* 45 C.F.R. § 160.103. PhRMA recommends that the Committee consider narrowing the definition of "health-related information," limiting it to personally identifiable information, to allow Maine residents to search for and receive general information about diseases and health conditions, while still protecting minors' privacy.

- **The statute's application to persons above the age of 13 limits the ability of teenagers to find health information and may conflict with federal law.** Teenagers are more likely than younger children to actively search the Internet for health information, so the Maine Legislature could significantly restrict the breadth of the law by adding a definition of "minor" to section 9551 that would restrict the applicability of the law to children under the age of 13. The federal Children's Online Privacy Protection Act (COPPA), 15 U.S.C. § 6501-06, requires parental consent before personal information may be knowingly collected online from a child under age 13. Congress has made the policy decision that teenagers should be able to search for, and look at, online information (including medical and scientific information) without obtaining their parents' prior consent. A broad application of the Maine law, particularly one like the current Maine statutory language that includes general health information as well as an individual's medical history, diagnosis or treatment, might conflict with COPPA, and prevent teenagers in Maine from finding or receiving useful health-related information. 15 U.S.C. Section 6502(d).

- **The statute may prohibit unsolicited receipt of a minor's information, because the statute does not contain a definition of "Collect" and does contain a prohibition on receiving health-related or personal information from minors.** Under the current law, if a minor submits a request for health information through a pharmaceutical company's website, or if a minor sends a pharmaceutical company a letter or e-mail, the company could face liability even if it did nothing to solicit the communication from the minor, and even if the company does not respond to the communication. The original bill defined the term "collect" to mean "to solicit, elicit, or ask for, with or without any form of incentive or enticement." LD 1183, § 9521(1). The inclusion of the phrase "or receive" drastically expands the threat of liability, not for soliciting but for passively receiving, information from minors.

- **Enforcement of the requirement that parental consent be obtained before the collection of information would be so onerous as to chill protected speech.** Drug company web sites frequently permit users to request further information about a disease, condition, or a medicine. It is not technologically practical to require companies to obtain

parental consent before minors submit such a request. Companies should be permitted to accept requests from all users, and upon determining that a particular request was submitted by a minor, either refuse to fulfill the request (and destroy the information collected) or seek parental consent prior to fulfilling the request. Without this alteration to section 9551(5), companies potentially face liability for a minor's action (submitting the request) over which the company has no control.

- **The broad description of unlawful uses of a minor's information sweeps in many important medical treatment communications.** Section 9552(2) of the current law prohibits any transfer of healthrelated or personal information if that information individually identifies the minor. There is no parental consent exemption, so the transfer of such information is prohibited even if the parent consents. This extremely broad measure may, for example, prohibit a physician from discussing a minor's treatment with another health care provider, billing an insurer for treatment of a minor, or calling in a prescription for a minor to a pharmacy. PhRMA recommends that the "unlawful use," if it is retained in a revised bill, be narrowed by focusing on the sale, offer or transfer of *individually identifiable* health-related or personal information if that information was unlawfully collected under section 9552(1) or will be unlawfully used.

- **The statute requires a company transferring information to control the use of that information after it has been transferred to another entity.** The current law would make an entity liable for transferring information about a minor if the *recipient* will use the information for predatory marketing purposes. As the subsequent use of information that is transferred is outside of the transferor's control, this prohibition should be limited to situations where the transferor *knows* that the recipient is planning an unlawful use.

- **The statute's broad description of predatory marketing sweeps in many important health-related communications.** The current law treats as prohibited predatory marketing the use of health-related or personal information regarding a minor for the purpose of marketing a product or service to that minor or promoting any course of action for the minor relating to a product. There is no parental consent exception from this rule. The prohibition could be used to prohibit physicians from discussing the proper use of a pharmaceutical product with a minor patient, even if the parent were present and consenting to the discussion. In theory, given the broad definition of "health-related information" the prohibition on using health-related information for marketing purposes could prevent pharmaceutical companies from advertising any product intended for minors or for a disease or condition common in minors.

- **The statute could be read to apply to information collected before the statute's effective date.** Many companies have collected information over the years from websites that provide either general health-related information or information about a specific disease or condition or a specific treatment or medicine. Because the statute is not clearly

applicable only to the collection of information from the statute's effective date, it could chill the communication of lawful and important health-related information to all consumers, because companies would have no way of determining which seekers of information were minors. Maine residents who are adults could thus be denied health-related information that they have affirmatively requested.

- **The statute's broad enforcement provisions risk creating unnecessary litigation and chilling important medical and scientific educational activities.** The current law provides for a private right of action for up to $750 per violation and the award of attorney's fees, thereby inviting class action lawsuits for violations of the law. Given the law's breadth and the difficulty of tailoring the law to protect minors without impinging on protected speech, the Attorney General should retain control over enforcement, because of her ability to set enforcement priorities, rather than expanding enforcement through a private right of action.

PhRMA would be happy to explain any or all of these concerns and we look forward to working with the Joint Committee to revise the current statute to more clearly address the concerns of Committee members.

In addition, we note that pharmaceutical companies are already subject to numerous laws and regulations, both state and federal laws, that govern collection of information from and marketing to consumers, some specific to minors. I have attached a list of federal laws, federal regulations, and Maine laws that are applicable to the activities that Public Law 2009, Chapter 230 is intended to cover.

Sincerely,

Marjorie E. Powell

cc: Margaret J. Reinsch, Esq.

Enclosure: Federal and Maine Laws Governing Collection and Marketing to Consumers by Pharmaceutical Companies

Federal and Maine Laws Governing Information Collection and Marketing to Consumers by Pharmaceutical Companies

Federal Statutes

- Children's Online Privacy Protection Act of 1998 ("COPPA"), 15 U.S.C. §§ 6501-6506 (2006) (regulating the online collection, use, and disclosure of personal information from children under age 13).

- Controlled Substances Act, 21 U.S.C. §§ 801 *et seq.* (2006) (governing the manufacture, importation, possession, use and distribution of certain controlled substances, including many pharmaceuticals).

- Federal Food, Drug, and Cosmetic Act of 1938 ("FDCA"), 21 U.S.C. §§ 301 *et seq.* (2006) (granting FDA authority to oversee the efficacy and safety of pharmaceutical products, including the regulation of advertising and labeling, among other authorities).

- Federal Trade Commission Act of 1914, 15 U.S.C. §§ 41-58 (2006) (prohibiting unfair methods of competition and unfair or deceptive acts or practices in or affecting commerce).

- Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), 42 U.S.C. § 201 *et seq.* and 1320d *et seq.* (2006) (restricting the collection and use of certain individually-identifiable health information, among other provisions).

- Health Information Technology for Economic and Clinical Health ("HITECH") Act, 42 U.S.C. 201 et seq. (2009) (applying certain HIPAA responsibilities directly to business associates, among other provisions) (amending HIPAA).

- Medicare and Medicaid Patient Protection Act of 1987 ("Anti-Kickback Statute"), 42 U.S.C. § 1320a-7b(b) (2006) (imposing criminal penalties for certain acts involving federally-funded health care programs, including the knowing and willful solicitation or receipt of payment to induce an entity to use an item or service that may be covered by such a program)

- Prescription Drug Marketing Act of 1987, *amended by* the Prescription Drug Amendments of 1992, 21 U.S.C. § 353 (2006) (establishing legal safeguards to ensure safe prescription drug distribution) (incorporated into the FDCA).

Federal Regulations

- Children's Online Privacy Protection Rule, 16 C.F.R. §§ 312.1-.12 (2009) (implementing COPPA's requirements concerning the online collection, use, and disclosure of personal information from children under age 13).

- Controlled Drugs, 21 C.F.R. § 1300-1399 (2009) (requirements for controlled substances).

- General Labeling Provisions, 21 C.F.R. § 201 (2009) (regulating drug labeling).

- HIPAA Privacy Rule, 45 C.F.R. pts. 160 & 164, subpts. A & E (2009) (implementing HIPAA privacy provisions, including restrictions related to marketing).

- Medication Guides for Prescription Drug Products, 21 C.F.R. § 208 (2009) (requirements for patient labeling for human prescription drug products).

- Prescription Drug Advertising, 21 C.F.R. § 202 (2009) (requirements for prescription drug advertising).

- Prescription Drug Marketing, 21 C.F.R. § 203 (2009) (implementing the Prescription Drug Marketing Act of 1987 and the Prescription Drug Amendments of 1992).

Maine Laws

- Confidentiality of Health Care Information, ME. REV. STAT. ANN. tit. 22, § 1711-C (2008) (establishing that an individual's health care information is confidential and may not be disclosed other than to the individual by the health care practitioner or facility, with certain exceptions).

- Confidentiality of Prescription Drug Information, ME. REV. STAT. ANN. tit 22, § 1711-E (2008) (restricting the use of patient-identifiable and prescriber-identifiable prescription information for marketing purposes).

- Drug Marketing Costs, ME. REV. STAT. ANN. tit 22, § 2698-A (2008) (requiring a manufacturer or labeler of prescription drugs dispensed in Maine that employs, directs or utilizes marketing representatives in Maine to report marketing costs for prescription drugs).

- Unfair Trade Practices Act, ME. REV. STAT. ANN. tit. 5, §§ 205A-214 (2008) (prohibiting unfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce).

- Uniform Deceptive Trade Practices Act, ME. REV. STAT. ANN. tit. 10, §§ 1211-1216 (2008) (providing that an entity may not, in the course of business, engage in conduct that creates a likelihood of confusion or misunderstanding).